DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 15, 2015

Smith and Nephew Incorporated
Ms. Laura Reynolds
Director Regulatory Affairs
970 Lake Carillon Drive, Suite 110
Saint Petersburg, Florida 33716

Re: K143115
Trade/Device Name: The VersaJet II Hydrosurgery System
Regulation Number: 21 CFR 880.5475
Regulation Name: Jet lavage
Regulatory Class: Class II
Product Code: FQH
Dated: June 11, 2015
Received: June 12, 2015

Dear Ms. Reynolds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143115

Device Name
The VersaJet II Hydrosurgery System

Indications for Use *(Describe)*
The VersaJet II Hydrosurgery System is intended for wound debridement (acute and chronic wounds, burns), soft tissue debridement, and cleansing of the surgical site in applications in which, in the physicians judgment, require sharp debridement and pulsed lavage irrigation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Wound Management
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F 727 392-6914 or 727 392-0797
Customer Care Center: 1 800 876-1261
www.smith-nephew.com

510(k) Summary

General Information

Submitters Name/Address: Smith & Nephew, Inc.
970 Lake Carillon Drive
Suite 110
St. Petersburg, FL 33716

Establishment Registration Number: 3006760724

Contact Person: Laura Reynolds
Director Regulatory Affairs

Phone Number: (727) 329-7702

Date Prepared: July 8, 2015

Device Description

Trade Name: VERSAJET™ II Hydrosurgery System

Generic/Common Name: Jet Lavage

Classification Name: Jet Lavage, 21 CFR 880.5475

Product Code: FQH

Predicate Device Information

Current Device	Predicate Device	510k#	Clearance Date
VERSAJET™ II Hydrosurgery System	VERSAJET™ II Hydrosurgery System	K110958	08/01/2011

Device Description

The VERSAJET™ II Hydrosurgery System consists of two basic system components: the reusable power console and the single-use, sterile (Ethylene Oxide) handpiece and tubing assembly. A footswitch is also available for operating the system.

The VERSAJET™ II Hydrosurgery System uses a pressurized stream of sterile fluid to cut, ablate and remove tissue and foreign matter from wounds and to resect and remove material in a variety of surgical applications. The device provides cutting, irrigation and evacuation in the same tool.

The high velocity stream of saline simultaneously washes the tissue surface and vacuums away foreign material from the wound. The fluid acts to tangentially ablate the surface of the tissue and

propel excised tissue and debris out of the wound. The debris and fluid are directed into the handpiece into a flexible tube, which carries the effluent to the drain or collection canister.

The pressure can be adjusted using either the footswitch or a sealed membrane switch on the front panel of the power console. Pressure settings range from 1-10 in factory pre-set increments, with the pressure increasing with each higher setting number, depending on user preference and the needs of a particular application.

Associated accessories include:

- VERSAJET EXACT Handpieces, single-use, sterile, in three configurations
- VERSAJET PLUS Handpieces, single-use, sterile, in three configurations
- Footswitch

Indications for Use

The VERSAJET II Hydrosurgery System is intended for wound debridement (acute and chronic wounds, burns), soft tissue debridement, and cleansing of the surgical site in applications in which, in the physicians judgment, require sharp debridement and pulsed lavage irrigation.

Summary Comparison between New and Predicate Devices

	New Device:	**Predicate Device:** **510(k)# K110958**
Trade Name:	**VERSAJET™ II Hydrosurgery System**	**VERSAJET™ II Hydrosurgery System**
Indications for Use:	Identical	Identical
Environment of use	Identical	Identical
VersaJet II Handpiece	Substantially Equivalent	Substantially Equivalent
Console case	Identical	Identical
Power Supply	Substantially Equivalent	Substantially Equivalent
Motor	Identical	Identical
Transmission	Substantially Equivalent	Substantially Equivalent
User Interface PCB	Substantially Equivalent	Substantially Equivalent
User Interface Housing	Substantially Equivalent	Substantially Equivalent
User Interface Chamber	Substantially Equivalent	Substantially Equivalent
Method of Sterilization:	Identical	Identical
Biocompatibility	Identical	Identical
Software	Identical	Identical

Table of Modifications

Modification	Reason For Change	Verification Testing Performed
Saline Bag Spike resin	Obsolete material	Comprehensive verification was completed which demonstrated acceptable device performance; retested biocompatibility
Retainer Fitting-changed from a metal injection molded part to a machined part; no specification changes	Improve manufacturability of the part	Comprehensive verification was completed which demonstrated acceptable device performance
Body Pump with Chamfer – increase length of dowel pin component	Length of the dowel pin was increased to assure full engagement between the pump body and retaining fitting; improve manufacturability	Comprehensive verification was completed which demonstrated acceptable device performance
High Pressure Hose - nylon material resin change	Obsolete material	Comprehensive verification was completed which demonstrated acceptable device performance; retested biocompatibility
Change to power supply Printed Circuit Board (PCB) layout	Address electrical issues of not turning on	Comprehensive verification and reliability was completed which demonstrated acceptable device performance
Changes to the oil seals, gasket and compression spring in the transmission	Increase reliability and address oil leakage	Comprehensive verification and reliability was completed which demonstrated acceptable device performance
Replacing passivation process with electro-polishing of the user interface components	Increase their corrosion resistance	Comprehensive verification and reliability was completed which demonstrated acceptable device performance
Replace a bronze bushing in the user interface chamber, with a Rulon™ bushing	Eliminate galvanic corrosion	Comprehensive verification and reliability was completed which demonstrated acceptable device performance
Minor modifications to comply with IEC 60601-1 3rd Edition safety standards	Compliance with safety standard	Device complies with the IEC 60601-1 3rd Edition series of electrical safety standards

Non-Clinical Tests (Bench)

Testing has been conducted to verify the modifications to the VERSAJET™ II Hydrosurgery System meet design specifications and demonstrate substantial equivalence to the predicate device.

The list below summarizes the bench testing undertaken and successfully completed for the VERSAJET™ II Hydrosurgery System device:

- Environmental testing of the device including the extremes of the operating range and under general operating room conditions.
- Reliability testing demonstrating that the modified components improved the reliability of the device.
- Monitoring of aerosols generated through the use of the device outside of the operating room in conditions such as out-patient surgery.
- Performance testing demonstrating that the effective cutting pressure range per console power setting, system priming, console cut off pressure function, and handset insertion, removal, engagement and disengagement forces are substantially equivalent to the predicate.

Biocompatibility on the VersaJet Handpieces has been successfully completed in accordance with applicable parts of ISO 10993 as follows:

- Cytotoxicity
- Skin Irritation
- Sensitization

Device complies with the following standards:

- ISO13485:2003, Medical Devices - Quality Management Systems
- ISO 14971:2012 Medical Devices - Application of Risk Management to Medical Devices
- ISO 15223-1:2012 Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied Part 1: General requirements.(General)
- ISO 15223-2:2010 Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied-Part 2: Symbol development, selection and validation. (General)
- BS EN 980:2008 Graphical Symbols for use in the labeling of Medical Devices
- BS EN 1041:2008 +A1:2013 Information Supplied by the Manufacturer with Medical Devices
- IEC 60601-1-2:2007(3rd edition) Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility -Requirements and tests, Interpretation Sheet
- IEC 60601-1:2005 (3rd edition). Medical Electrical Equipment - Part 1: General Requirements for Safety
- ISO 11135: 2014 Medical Devices - Validation and routine control of ethylene oxide sterilization
- ISO 11607-1:2006 Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 10993-1:2009 Biological evaluation of medical devices Part 1: Evaluation and testing with a risk management process

- ISO 10993-10:2010 Biological evaluation of medical devices- Part 10:Tests for irritation and skin sensitization

Conclusions

In establishing substantial equivalence to the currently marketed predicate devices, Smith & Nephew, Inc. evaluated the indications for use, materials, technology, product specifications and energy requirements of the device. Performance testing, biocompatibility testing and electrical safety testing has been successfully completed to demonstrate that the VERSAJET™ II Hydrosurgery System is substantially equivalent to the predicate device for the intended use.